

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Chapman on July 18, 2008.

The application has been amended as follows:

#### In The Claims

Claim 10, lines 1-2 delete "wherein said lateral hinges is the knee hinge of claim 1 and wherein said medial hinge is the knee hinge of claim 1".

Claim 11, lines 1-2 delete "wherein said medial hinge is the knee hinge of claim 1 and wherein said lateral hinge is the knee hinge of claim 1".

Claim 19, line 2, after "1" insert --.--

The following is an examiner's statement of reasons for allowance: the prior art of record fails to teach or fairly suggest to one having ordinary skill in the art a hinge having a variable center of rotation comprising an inner shell, outer shell and a middle shell, wherein "said inner shell further comprising an inner shell protuberance; said middle shell further comprising a middle shell protuberance, and a middle shell slot through which said inner shell protuberance tracks, wherein said inner shell protuberance tracking constrains said middle shell

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rotation of said middle shell relative to said inner shell; said outer shell further comprising an outer shell slot through which said middle shell protuberance tracks, wherein said middle shell protuberance tracking constrains said outer shell rotation of said outer shell relative to said middle shell” in combination with the other recited elements of claim 1.

The prior art also fails to teach a hinge comprising “an inner shell, a middle shell, an outer shell, and a cover shell, said middle shell rotatably engaged to said inner shell and having an inner-middle shell co-axis and middle shell rotation, said outer shell rotatably engaged to said middle shell and having a middle-outer shell co-axis and outer shell rotation, wherein said inner shell and cover shell do not rotate, and wherein said inner-middle shell co-axis is located at the center of the inner shell, and said middle-outer shell co-axis is located off-center of said middle shell; said inner shell further comprising an inner shell protuberance; said middle shell further comprising a middle shell protuberance, and a middle shell slot through which said inner shell protuberance tracks, wherein said inner shell protuberance tracking constrains said middle shell rotation of said middle shell relative to said inner shell; aid outer shell further comprising an outer shell protuberance and an outer shell slot through which said middle shell protuberance tracks, wherein said middle shell protuberance tracking constrains said outer shell rotation of said outer shell relative to said middle shell” in combination with the other recited elements presently recited in claim 7.

The prior art even further fails to teach or fairly recited a method for treating a knee pathology comprising the step of “applying an off-loading force to the knee, wherein said rotational force and said off-loading force is applied repeatedly during every flexion/extension cycle so as to correct the knee pathology; wherein said application of rotational force and off-loading force is generated by a combination of a first hinge and a second hinge, the first hinge located medial to the knee and the second hinge located lateral to the knee, wherein said first hinge has a first variable center of rotation and said second hinge has a second variable center of rotation, wherein the first variable center of rotation is defined by tracking of a middle shell protuberance in the medial hinge with an outer shell slot in the medial hinge over a first flexion range, and tracking of an inner shell protuberance in the medial hinge with a middle shell slot in the medial hinge over a second flexion range; and the second variable center of rotation is defined by tracking of a middle shell protuberance in the lateral hinge with an outer shell slot in the lateral hinge over a third flexion range, and tracking of an inner shell protuberance in the lateral hinge with a middle shell slot in the lateral hinge over a fourth flexion range” in combination with the other recited steps in claim 13.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-

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4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/  
Primary Examiner  
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kml  
July20, 2008